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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,021	07/11/2003	Hiroaki Waki	030471	2701

38834 7590 06/28/2006

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EXAMINER

LUDLOW, JAN M

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/617,021	Applicant(s) WAKI, HIROAKI	
	Examiner Jan M. Ludlow	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/4/2003</u> . | 6) <input type="checkbox"/> Other: ____. |

1. Figures 5-6 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 3-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abedi (US6413431).

Abedi teaches a chromatograph including UV and MS detectors. The fraction collector is triggered when the presence of a compound of interest is detected by UV and/or MS detection (col. 6, lines 58-62; col. 13, line 59-col. 14, line 2). Switching valves such as that controlling the fraction collector/waste connection are under computer control (col. 3, line 37). A time delay between the MS, UV and fraction collector is determined using a standard (col. 14, lines 10-15).

Abedi fails to explicitly teach a binary converter, logical operator or a shift time canceller.

It is the examiner's position that the teaching that the fraction collector is triggered when the presence of a compound of interest is detected by UV and/or MS detection suggests assigning a binary value to portions of each the chromatograms derived from the UV and MS detectors, e.g., peak detected yes/no in UV; peak detected yes/no in MS, and a logical operation of "AND" or "OR" in that either or both of the detectors can be used to trigger the fraction collector. Further, it would have been obvious to provide a binary converter and a logical operator to do so in a computer controlled device. It would have been further obvious to provide a time shift canceller in order account for the time shifts to synchronize the data collection, comparison and fraction collection as the determination of delay times suggests.

5. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Abedi as applied to claims above, and further in view of Fischer et al (2002/0121468).

Fischer teaches a chromatograph including UV (13), MS (18) and ELSD (18 or 70) detectors. The fraction collector is triggered under automatic control when the

presence of a compound of interest is detected by one or more of the detectors [0027]. A time delay between the MS, UV, ELSD and fraction collector is determined using a standard and used to automatically control the apparatus ([0010-0011, 0029]).

It would have been obvious to provide an ELSD detector in Abedi in order to provide an alternative destructive detector and/or a quantitative detector as taught by Fischer. It would have been obvious use the chromatogram generated to control the fraction collector in order to use one or more known characteristics at the one or more detectors to control the collector as taught by Fischer.

6. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer (2002/0121468).

Fischer teaches a chromatograph including UV (13), MS (18) and ELSD (18 or 70) detectors. The fraction collector is triggered under automatic control when the presence of a compound of interest is detected by one or more of the detectors [0027]. A time delay between the MS, UV, ELSD and fraction collector is determined using a standard and used to automatically control the apparatus ([0010-0011, 0029]).

Fischer fails to explicitly teach a binary converter, logical operator or a shift time canceller.

7. It is the examiner's position that the teaching that the fraction collector is triggered when the presence of a compound of interest is detected by one or more of the detectors suggests assigning a binary value to portions of each the chromatograms derived from the detectors, e.g., peak detected yes/no in UV; peak detected yes/no in MS; peak detected yes/no in ELSD, and a logical operation of "AND" or "OR" in that one

or more (e.g., all) of the detectors can be used to trigger the fraction collector. Further, it would have been obvious to provide a binary converter and a logical operator to do so in a computer controlled device. It would have been further obvious to provide a time shift canceller in order account for the time shifts to synchronize the data collection, comparison and fraction collection as the determination of delay times suggests.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

9. Kibbey (5670054) corresponds to WO 97/38303 cited as an X reference on the Search Report of record, but does not teach the instant invention because it uses UV and MS measurements in an analytical HPLC to identify peaks with UV alone in a preparative HPLC.

10. Connelly (5,938,932) corresponds to WO 99/25452 cited in the Search Report. Connelly teaches an HPLC system with UV detector 516, mass spec 510 and ELSD 512. Chromatogram signals from a first chromatogram are compared to threshold values (col. 8, lines 15-17) and signals from the second chromatogram are compared to elution times (col. 8, lines 32-37). The UV detector can be used for secondary confirmation of peak and compound presence (col. 9, lines 15-20). Connelly fails to teach using the resultant signal to control a fraction collector.

11. Umemura cited in the Search Report teaches using a UV detector to control measurement timing in a Mass Spec.

12. Abedi corresponds to EP 1162456 cited in the Search Report.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (571) 272-1260. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Jan M. Ludlow
Primary Examiner
Art Unit 1743

Jml
June 23, 2006